

III. Remarks

Claims 1-17, 20, 22-44, 56-61, 66, 67, 70, 71, 74-76, 81, 82, 84-96, 101-103, 106-110, and 112-122 were previously pending. Claims 93-96, 101-103, 106-110, 112, 113, 121, and 122 were previously withdrawn from consideration. Claims 1, 2, 4-9, 20, 22, 81, 82, 84, 85, and 120 are canceled by the present paper without prejudice to or disclaimer of the subject matter therein. No claims are currently added.

Applicants appreciate the indication of allowance with respect to claims 114-119. Applicants note that there is a discrepancy between the Office Action Summary and substantive contents of the Office Action regarding the other claims. In particular, the Office Action Summary indicates that claims 91 and 92 are rejected and claims 1-17, 20, 22-44, 56-61, 66-71, 74-76, 84-90, and 120 are objected to, while the detailed portion of the Office Action indicates that claims 91 and 92 are objected to and claims 1-17, 20, 22-44, 56-61, 66-71, 74-76, 84-90, and 120 are rejected. Accordingly, Applicants will address the rejections and objections as set forth in the detailed portion of the Office Action rather than the Summary.

Applicants appreciate the indication that claims 91 and 92 would be allowable if rewritten in independent form. To that end, claim 91 has been rewritten in independent form. Claim 92 depends from and further limits claim 91. Accordingly, claims 91 and 92 are in condition for allowance.

Reconsideration of claims 3, 10-17, 23-44, 56-61, 66, 67, 70, 71, 74-76, 86-92, and 114-119 is respectfully requested in light of the above amendments and the following remarks.

Premature Final Rejection

As a preliminary matter, Applicants request that the finality of the Office Action be withdrawn. As set forth clearly in MPEP §706.07(a):

“Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c)....”

In the present case, the new ground of rejection for at least claims 88 and 89 under 35 U.S.C. §103 is neither necessitated by an amendment made by the Applicant nor information submitted in an IDS filed under 37 CFR 1.97(c). In the previous Office Action—mailed April 13, 2007—claims 88 and 89 were objected to as being dependent upon a rejected base claim. In response Applicants amended claim 88 to be in independent form. Claim 89 remains as originally filed and depends from and further limits claim 88. Accordingly, the new rejection is not necessitated by an amendment made by the Applicants. Further, the references cited as supporting the new ground of rejection were not submitted in an IDS filed during the period set forth in 37 CFR 1.97(c). Accordingly, the new rejection is not necessitated by information submitted in an IDS filed under 37 CFR 1.97(c).

In this context, MPEP §706.07(a) clearly states that:

“[A] second or any subsequent action on the merits in any application ... will not be made final if it includes a rejection, on newly cited art, ... in spite of the fact that other claims may have been amended to require newly cited art.”

Thus, Applicants assert that the current Office Action has been improperly made final. For at least these reasons Applicants request that the finality of the Office Action be withdrawn.

Rejections under 35 U.S.C. § 102

The Office Action indicated that **claims 56-61** are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,401,269 to Buttner-Janz et al. (“the Buttner-Janz patent”). Therefore, to sustain the rejection of the claims 56-61 the Buttner-Janz patent must disclose all of the claimed elements of each claim.

With respect to independent claim 56, the Buttner-Janz patent at least fails to disclose an implant having all of the recited features of the claim, including “wherein the central body has an upper and a lower contact surface, and wherein in the absence of a compressive load, an upper shoulder is recessed into a portion of the perimeter of the upper contact surface and a lower shoulder is recessed into a portion of the perimeter of the lower contact surface.” (emphasis added). As shown below, Fig. 8B of the present application illustrates an exemplary embodiment

of a central body having upper and lower shoulders 90 and 92 recessed into a portion of the perimeter of the respective contact surfaces.

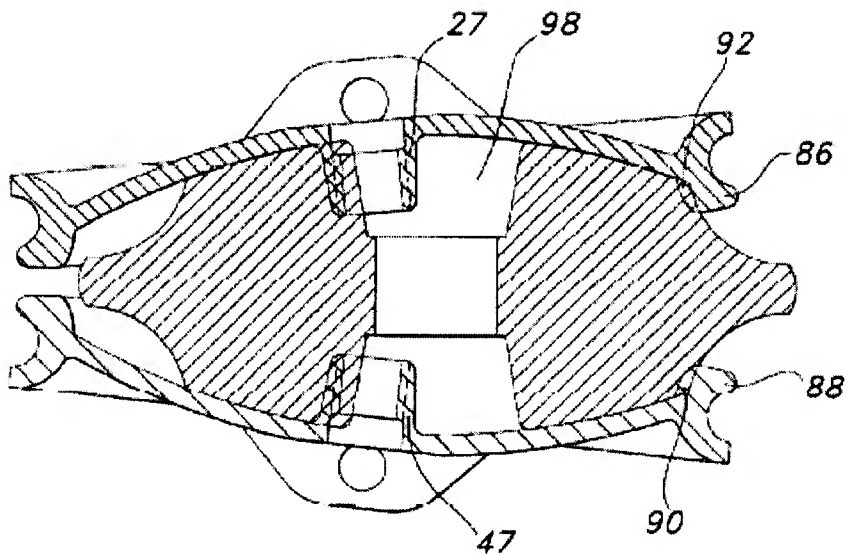
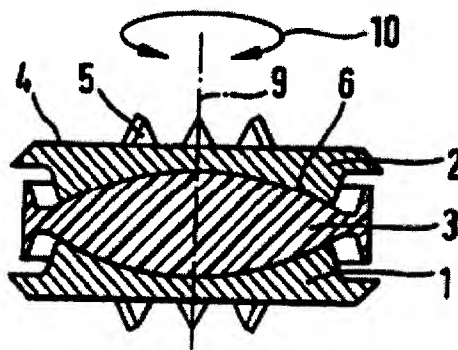
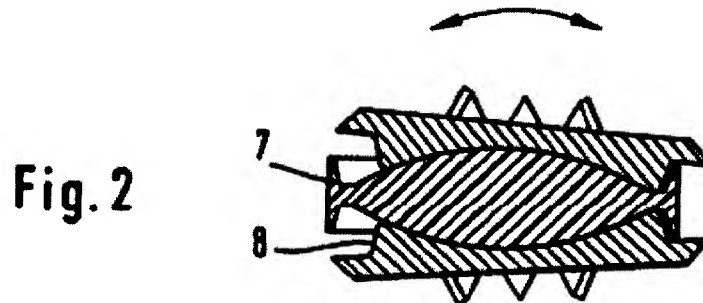


FIG 8B

The cited portions of the Buttner-Janz patent simply do not disclose having shoulders recessed in the upper and lower contact surfaces as recited. Rather, as shown in Figs. 1 and 2 of the Buttner-Janz patent, reproduced below, the collar 7 surrounding and defining the perimeter of the prosthesis core 3 is not recessed into the articular surfaces 6. Rather, the collar 7 projects outwardly at an increased height from the articular surfaces 6. Further, the area just inside the collar 7 having a reduced height relative to the collar cannot be considered a shoulder as recited because it is not recessed into a portion of the perimeter as required.

Fig. 1





For at least this reason, the Buttner-Janz patent fails to disclose all of the limitations of independent claim 56. Claims 57 and 58 depend from and further limit claim 56. Therefore, for at least these reasons Applicants respectfully request that the §102 rejection of claims 56-58 be withdrawn.

Similar to independent claim 56, independent claim 59 requires “wherein an upper shoulder extends around a portion of the perimeter of the upper contact surface and a lower shoulder extends around a portion of the perimeter of the lower contact surface and further wherein the upper shoulder defines a ledge indented into and around the perimeter of the upper contact surface of the central body.” As discussed above, the Buttner-Janz patent fails to disclose such limitations. Therefore, for at least the same reasons, the Buttner-Janz patent fails to disclose an implant with all of the recited limitations of claim 59. Claims 60 and 61 depend from and further limit claim 59. Therefore, Applicants respectfully request that the §102 rejection of claims 59-61 be withdrawn.

The Office Action also indicated that **claims 81, 82, 84, 85, and 120** are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,674,296 to Bryan et al. (“the Bryan patent”). However, these claims are canceled by the present paper rendering this rejection moot. Accordingly, Applicants will not address this rejection at this time.

Rejections under 35 U.S.C. § 103

The Office Action indicated that **claims 1, 4-9, 13-15, and 20** are rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of U.S. Patent No. 5,868,796 to Buechel et al. (“the Buechel patent”). Applicants respectfully traverse the rejection

of claims 1, 4-9, 13-15, and 20 on the grounds that these references are defective in establishing a *prima facie* case of obviousness. However, claims 1, 4-9, and 20 are canceled by the present paper and claims 13-15 are amended to depend from and further limit claim 3, rendering this rejection moot. Accordingly, Applicants will not address this rejection at this time

The Office Action also indicated that **claims 2, 10-12, 22, 24-37, and 120** are rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of the Buechel patent in view of the Bryan patent. Claims 2, 22, and 120 are canceled by the present paper. Further, claims 10-12 are amended to depend from and further limit claim 3, while claims 24-37 are amended to depend from and further limit claim 23. Accordingly, this rejection is moot and Applicants will not address this rejection at this time.

The Office Action also indicated that **claims 74-76** are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,002,576 to Fuhrmann et al. (“the Fuhrmann patent”) in view of U.S. Patent No. 6,132,465 to Ray et al. (“the Ray patent”). Applicants respectfully traverse the rejection of claims 74-76 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

With respect to independent claim 74, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited features of the claim, including “at least two opposing shells, a central body disposed between the two opposing shells, and at least one sealable opening in one of the at least two opposing shells for the introduction of a lubricant into the implant between the central body and the opposing shells after the implant has been assembled.” Rather, the opening 21 in the cover plate 3” of the Fuhrmann patent “serves to fill the interior with viscoelastic material—or, together with a similar opening, as ventilation.” Col. 4, Lines 10-12. In the Fuhrmann patent, the viscoelastic material fills a closed corrugated tube 1 to create the central spring body. Col. 2, Lines 52-67. In other words, the viscoelastic material 2 is part of the central body of the Fuhrmann device. Thus, the opening 21 is not for the “introduction of a lubricant into the implant between the central body and opposing shells,” as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form the central spring body. The viscoelastic material cannot be introduced between a

central body and opposing shells because the viscoelastic material is the central body. Similarly, the hydrogel core 22 of the Ray patent is positioned within the constraining jacket 24 of the prosthetic nucleus 20 and “is configured to imbibe fluids, expanding from a dehydrated state to a hydrated state.” Col. 6, ll. 63-65. The fluids simply are not positioned between a central body and opposing shells as required. Rather, the fluids are positioned within the hydrogel core. Accordingly, for at least this reason, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited elements of claim 74. Therefore, Applicants respectfully request that the §103 rejection of claim 74 over the Fuhrmann and Ray patents be withdrawn.

With respect to amended independent claim 75, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited features of the claim, including “a central body and a lubricant encapsulated within the implant between the central body and a structure having at least one opening for the introduction of the lubricant into the structure, wherein the structure includes two shells and a sleeve extending between the shells, and the opening is included in at least one of the shells.” As discussed above with respect to claim 74, the Fuhrmann and Ray patents simply do not disclose such limitations. Claim 76 depends from and further limits claim 75. Accordingly, the Applicants request that the §103 rejection of claims 75 and 76 over Fuhrmann and Ray patents be withdrawn.

The Office Action also indicated that **claim 3** is rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of the Buechel patent in view of the Fuhrmann patent. Applicants respectfully traverse the rejection of claim 3 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

Claim 3 requires, “a flexible sheath extending between edges of the opposing shells, having an inner surface that, together with the inner surfaces of the rigid shells, defines a cavity containing the central body; and a liquid lubricant, which occupies at least a portion of the cavity.” However, even when combined the Buttner-Janz, Bryan, and Fuhrmann patents fail to disclose such limitations. In that regard, the current Office Action itself stated with respect to claims 74-76 that “Fuhrmann et al. did not teach of the introduction of a lubricant between the central body and the opposing shells; as claimed by applicant.” Claim 3 similarly requires a

liquid lubricant occupy a cavity defined by the inner surfaces of the rigid shells and the flexible sheath that contains the central body. Accordingly, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to teach all of the claimed elements of independent claim 3. Therefore, Applicants respectfully request that the §103 rejection of claim 3 be withdrawn.

Further, claims 10-15 have been amended to depend from and further limit independent claim 3. Therefore, for at least the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 10-15.

The Office Action also indicated that **claims 16, 17, 23, 28-44, 66, 67, 70, 71, and 86-90** are rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of the Buechel patent in view of the Bryan patent in view of the Fuhrmann patent. Applicants respectfully traverse the rejection of claims 16, 17, 23, 28-44, 66, 67, 70, 71, 86-89, and 90 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art**. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does**. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741 (emphasis added).

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that the examiner has not factually supported a *prima facie* case of obviousness with respect to each of these claims in the present case.

With respect to independent claim 16, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to disclose an implant having all of the recited limitations, including “wherein at least one of the rigid opposing shells further comprises a closable passage between its outer surface and its inner surface ... wherein the closable passage is configured in a manner that permits the introduction of a lubricant into the implant between the central body and the opposing shells.” As discussed above with respect to claims 74 and 75, the opening 21 of the Fuhrmann disc is not for the “introduction of a lubricant into the implant between the central body and opposing shells,” as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form a central spring body. As such, the viscoelastic material cannot be introduced between a central body and opposing shells because the viscoelastic material is the central body. Further, the current Office Action itself stated with respect to claims 74-76 that “Fuhrmann et al. did not teach of the introduction of a lubricant between the central body and the opposing shells; as claimed by applicant.” Accordingly, even when combined these references fail to disclose the recited limitations.

Further, there is no reason for combining the opening 21 of the Fuhrmann disc with the devices of the Buttner-Janz patent and the Bryan patent other than hindsight. Recently, the Supreme Court ruled that the “teaching, suggestion, or motivation (TSM) test” still applies, but should be used in a more “expansive and flexible” manner. *KSR Int’l. Co. v. Teleflex Inc.*, slip opinion at 14-15 (2007). The Court stated that

“A patent composed of several elements is **not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of

what, in some sense, is already known.” Id. at 14-15, emphasis added.

In the present case, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Bryan patent. The Office Action states that “it would have been obvious ... to modify the device of Buttner-Janz/Bryan et al., as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant. However, the devices of the Butter-Janz and Bryan patents include substantially solid core or central pieces. The central pieces of the Buttner-Janz and Bryan patents are not formed by filling a tube with viscoelastic material as in the Fuhrmann patent. Thus, one would not modify the devices of the Buttner-Janz and Bryan patents to fill the implant with a viscoelastic material to create a central body as in the Fuhrmann patent. Further, there is no indication why one would combine ventilation with the Buttner-Janz and Bryan devices. Accordingly, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Bryan patent. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 16. Claim 17 depends from and further limits claim 16. Therefore, Applicants respectfully request that the §103 rejection of claims 16 and 17 be withdrawn.

With respect to independent claim 23, even when combined the Buttner-Janz patent, the Bryan patent, and the Fuhrmann patent fail to disclose an implant having all of the recited limitations, including “an elastic sheath disposed between the upper and lower shells and external to the central body, comprising an inner surface, an outer surface, an upper edge attached to the upper shell, and a lower edge attached to the lower shell; wherein the inner surface of the sheath and the inner surfaces of the shells define an enclosed cavity; and a lubricant disposed within the enclosed cavity.” As discussed above, the current Office Action itself stated with respect to claims 74-76 that “Fuhrmann et al. did not teach of the introduction of a lubricant between the central body and the opposing shells; as claimed by applicant.” Even when combined these references fail to disclose an implant with a lubricant disposed within an enclosed cavity defined

by the inner surface of a sheath and the inner surfaces of the shells with a central body positioned therein. Accordingly, even when combined these references fail to disclose the recited limitations of claim 23. Applicants request that the §103 rejection of claim 23 over the Buttner-Janz, Buechel, Bryan, and Fuhrmann patents be withdrawn.

Further, claims 24-40 now depend from and further limit claim 23. Therefore, for at least the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 24-40.

With respect to independent claim 41, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, and the Fuhrmann patent fail to disclose an implant having all of the recited limitations, including

“an upper and a lower rigid, opposed biocompatible concavo-convex shell, each comprising: ... a first ridge circumscribing the contact area of the inner concave surface and extending axially toward the opposing shell; ... a deformable, resilient central body disposed between the inner, smooth concave surfaces of the upper and lower shells, comprising: ... a shoulder circumscribing each of the smooth convex upper and lower surfaces and adapted to contact the first ridge of the adjacent shell and limit the relative motion of the shell with respect to the central body; a laterally extending equatorial ridge disposed between the first ridge of the upper concavo-convex shell and the first ridge of the lower concavo-convex shell.”

In particular, even when combined the cited references do not disclose a central body having a shoulder circumscribing upper and lower surfaces for contacting the ridge of a shell—the ridge circumscribing a contact area of the inner surface of the shell—and a laterally extending equatorial ridge disposed between the ridge of the upper shell and the ridge of the lower shell, as required. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 41. Claims 42-44, 66, 67, 70, and 71 depend from and further limit claim 41. Further, claim 43 requires “a lubricant disposed within the implant cavity,” which as discussed above is not disclosed by the cited references. Therefore, Applicants respectfully request that the §103 rejection of claims 41-44 over the Buttner-Janz, Buechel, Bryan, and Fuhrmann patents be withdrawn.

With respect to independent claim 86, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, and the Fuhrmann patent fail to disclose an implant having all of the recited limitations, including “two shells interconnected by a sleeve to form a cavity therein, and a central body having at least one indentation therein positioned within the cavity, wherein ... at least one of the shells includes an opening to allow introduction of a lubricant into the cavity.” As discussed above, the opening 21 of the Fuhrmann disc is not configured for the introduction of a lubricant into cavity having a central body positioned therein. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form a central spring body. As such, the viscoelastic material cannot be introduced into a cavity having a central body positioned therein because the viscoelastic material is the central body. Further, as discussed above, there is no reason for combining the opening 21 of the Fuhrmann disc with the devices of the Buttner-Janz patent, the Buechel patent, and the Bryan patent other than hindsight. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 86. Claim 87 depends from and further limits claim 86. Therefore, Applicants respectfully request that the §103 rejection of claims 86 and 87 be withdrawn.

With respect to independent claim 88, even when combined the Buttner-Janz, Buechel, Bryan, and Fuhrmann patents fail to disclose an implant having all of the recited features, including “two shells interconnected by a sleeve to form a cavity therein, and a central body having at least one indentation therein positioned within the cavity, wherein at least one of the shells includes a retaining post that extends into the indentation and at least one of the shells includes an opening to allow introduction of a lubricant into the cavity, wherein the opening is adapted to being sealed with a plug tool having a handle and a detachable integral plug associated therewith.” Again, the opening 21 of the Fuhrmann disc is not configured for the introduction of a lubricant into cavity having a central body positioned therein. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form a central spring body. As such, the viscoelastic material cannot be introduced into a cavity having a central body positioned therein because the viscoelastic material is the central body. Further, as

discussed above, there is no reason for combining the opening 21 of the Fuhrmann disc with the devices of the Buttner-Janz patent, the Buechel patent, and the Bryan patent other than hindsight. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 86. Claim 89 depends from and further limits claim 88. Therefore, Applicants respectfully request that the §103 rejection of claims 88 and 89 be withdrawn.

With respect to claim 90, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, and the Fuhrmann patent fail to disclose a method having all of the recited steps, including “[a] method of introducing the lubricant into the implant of claim 86 comprising slightly compressing the implant to remove excess air, and injecting the lubricant into the opening.” In particular, none of the references discloses “slightly compressing the implant to remove excess air, and injecting the lubricant into the opening,” as recited. Further, the Office Action still makes no mention of how or what portions of the references may be interpreted to include such limitations. The provisions of 37 C.F.R. §1.104 specify that an Office Action must identify the relevant portions of a reference used to reject claims under §103. Specifically, §1.104 states, “[w]hen a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable.” The present Office Action does not reference a figure, a passage of text, or a reference numeral that would indicate which of the several embodiments of each of the references the Examiner deems to disclose the recited elements. Therefore, for at least these reasons a *prima facie* case of obviousness has not been established. Applicants respectfully request that the §103 rejection of claim 90 be withdrawn.

IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims under consideration are in condition for allowance. Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



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